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SECTION 5: 510(k) SUMMARY

Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, UT 84095

CONTACT:
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JAN 21 2010

DATE PREPARED:
December 21, 2009

TRADE OR PROPRIETARY NAME:
ALIMAXX-B™ Uncovered Biliary Stent System

CLASSIFICATION/ NAME:
Class II, Biliary Catheter and Accessories (21CFR §876.5010), Product Code FGE

PREDICATE DEVICES:
ALIMAXX-B™ Uncovered Biliary Stent System (K072720)

DEVICE DESCRIPTION:
The ALIMAXX-B™ Uncovered Biliary Stent System is a sterile, single-use, self-expanding Nitinol stent that is supplied with the stent pre-loaded on the triaxial delivery catheter of the delivery system. The delivery system is available in two designs, one for endoscopic placement (working length is 185 cm) and another for transhepatic placement (working length is 80 cm).

INTENDED USE:
The ALIMAXX-B™ Uncovered Biliary Stent System is intended for palliation of malignant strictures in the biliary tree.

TECHNOLOGICAL COMPARISON:
The modifications proposed are being made to the endoscopic delivery system catheter to improve visibility during stent placement. These changes are not being made to the transhepatic delivery system catheter. The modified device has the identical intended use and employs the same fundamental technology as the predicate device.

The proposed design, material, and labeling changes that triggered the submission of this notification consist of the following:

- Segments of the endoscopic delivery system catheter shall have material and colorant changes made to improve the endoscopic and fluoroscopic visibility of the position of the stent during placement.
- Changes have been made to the Instructions for Use to identify Merit Medical Systems, Inc. (Merit) as the manufacturer of the device, as Alveolus Inc., the submitter of the original 510(k), is no longer the legal manufacturer. Additional changes in instruction have been added to address the modifications made to the delivery system catheter's increased visibility during endoscopic placement of the stent.

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Note that the proposed modifications are only to be made to the endoscopic delivery system catheter. Neither the transhepatic delivery system catheter nor the biliary stent will be modified.

PERFORMANCE TESTING:
Design verification and design validation studies have been completed. The results demonstrate that the risks associated with the design modifications, as identified in Merit's ALIMAXX-B™ uncovered biliary stent system Clinical Risk Assessment (CRA), have met all of their pre-determined acceptance criteria. Additionally, acceptable controls used to mitigate the identified risks have been incorporated into the devices specifications.

SUMMARY OF SUBSTANTIAL EQUIVALENCE:

Based on:

- Merit's conformance with Design Control requirements;
- Analyses of risks associated with the modified device; and
- Results of verification and validation tests performed to address risks identified in Merit's Risk Assessment demonstrating that predetermined acceptance criteria have been met and risks have been adequately controlled,

Merit concludes that the modified devices are as safe and effective as, and perform as well as, or better than, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN 21 2010

Ms. Carol Holloway, RAC
Director of Regulatory Affairs
Merit Medical Systems, Inc.
1600 West Merit Parkway
SOUTH JORDAN UT 84095

Re: K093947
Trade/Device Name: ALIMAXX-B™ Uncovered Biliary Stent System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: January 6, 2010
Received: January 8, 2010

Dear Ms. Holloway:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at(301) 796-5484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093947

Device Name: ALIMAXX-B™ Uncovered Biliary Stent System

Indications For Use:

The ALIMAXX-B™ Uncovered Biliary Stent System is intended for palliation of malignant strictures in the biliary tree.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093947